IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC., Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 16-976 (SLR)

APOTEX INC. AND APOTEX CORP.'S
ANSWER AND AFFIRMATIVE DEFENSES
TO PLAINTIFFS' COMPLAINT

Defendants Apotex Inc. and Apotex Corp. (collectively, "Defendants" or "Apotex"), by and through their undersigned counsel, for their Answer and Affirmative Defenses to the Complaint filed by Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Plaintiffs"), state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Apotex denies all allegation in Plaintiffs' Complaint except those specifically admitted below.

THE PARTIES

1. Plaintiff Astellas Pharma Inc. is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. Astellas Pharma Inc. was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 1, and on that basis denies these allegations.

2. Plaintiff Astellas Ireland Co., Ltd. ("AICL") is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL is a subsidiary of Plaintiff Astellas Pharma Inc.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 2, and on that basis denies these allegations.

3. Plaintiff Astellas Pharma Global Development, Inc. ("APGD") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062. APGD is a subsidiary of Plaintiff Astellas Pharma Inc.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 3, and on that basis denies these allegations.

4. On information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. On information and belief, Apotex Inc., by itself and/or through its affiliates and agents, is in the business, inter alia, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

ANSWER: Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Apotex admits that Apotex Inc. seeks FDA approval for and manufactures generic pharmaceutical products that are distributed and sold in the United States, including the State of Delaware. Apotex denies all remaining allegations of Paragraph 4.

5. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 N. Commerce Parkway, Weston, Florida 33326. On information and belief, Apotex Corp., by itself and/or through its affiliates and agents, is in the business, inter alia, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

ANSWER: Apotex admits that Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 N.

Commerce Parkway, Weston, Florida 33326. Apotex admits that Apotex Inc. seeks FDA approval for and manufactures generic pharmaceutical products that are distributed and sold in the United States, including the State of Delaware, in some cases by Apotex Corp. Apotex denies all remaining allegations of Paragraph 5.

6. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

ANSWER: Denied.

7. On information and belief, Defendants Apotex Inc. and Apotex Corp. have cooperated and assisted in the preparation and filing of Apotex's Abbreviated New Drug Application ("ANDA") No. 209434 and will be involved in the manufacture, importation, marketing and sale of the drug that is the subject of ANDA No. 209434 if it is approved.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 7.

NATURE OF THE ACTION

8. This is an action for patent infringement of United States Patent Nos. 7,342,117 ("the '117 patent"), 7,982,049 ("the '049 patent"), 8,835,474 ("the '474 patent"), and RE44,872 ("the '872 patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to Apotex's filing of ANDA No. 209434 under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration ("FDA") approval to market generic pharmaceutical products.

ANSWER: Apotex admits that Plaintiffs purport to bring this action for infringement of United States Patent Nos. 7,342,117 ("the '117 patent"), 7,982,049 ("the '049 patent"), 8,835,474 ("the '474 patent"), and RE44,872 ("the '872 patent"), arising from the filing of ANDA No. 209434 with the FDA. Apotex denies all remaining allegations of Paragraph 8.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

ANSWER: Admitted.

10. This Court has personal jurisdiction over each Defendant for purposes of this civil action.

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, without admitting that personal jurisdiction in this judicial district is proper, Apotex states that it does not contest personal jurisdiction for the purposes of this action only. Apotex denies all remaining allegations of Paragraph 10.

11. This Court has jurisdiction over Apotex Inc. On information and belief, Apotex Inc. the parent corporation of Apotex Corp.

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, without admitting that personal jurisdiction in this judicial district is proper, Apotex states that it does not contest personal jurisdiction for the purposes of this action only. Apotex denies all remaining allegations of Paragraph 11.

12. This Court has jurisdiction over Apotex Corp. On information and belief, Apotex Corp. is a Delaware company.

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, without admitting that personal jurisdiction in this judicial district is proper, Apotex states that it does not contest personal jurisdiction for the purposes of this action only. Apotex denies all remaining allegations of Paragraph 12, except that Apotex admits that Apotex Corp. is a Delaware corporation.

13. On information and belief, Apotex, directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this Judicial District. On information and belief, Apotex has purposefully conducted and continues to conduct business in Delaware, and Delaware is a likely destination of Apotex's generic drug products. On information and belief, Apotex has purposefully availed itself of the rights and benefits of the laws of the State of Delaware, having previously submitted to personal jurisdiction in this Court and having engaged in systematic and continuous contacts with the State of Delaware.

ANSWER: Without admitting that personal jurisdiction in this judicial district is proper, Apotex states that it does not contest personal jurisdiction for the purposes of this action only. Apotex denies all remaining allegations of Paragraph 13.

14. On information and belief, Apotex Inc. and Apotex Corp. are agents of each other with respect to the development, regulatory approval, marketing, sale and/or distribution of generic drug products. On information and belief, the acts of Apotex Inc. and Apotex Corp. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of each other.

ANSWER: Without admitting that personal jurisdiction in this judicial district is proper, Apotex states that it does not contest personal jurisdiction for the purposes of this action only. Apotex denies all remaining allegations of Paragraph 14.

15. On information and belief, Apotex filed an abbreviated new drug application seeking approval from the FDA to market and sell pharmaceutical products containing the compound mirabegron as active ingredient, for the treatment of overactive bladder, prior to the expiration of each of the '117, '049, '474, and '872 patents.

ANSWER: Admitted.

16. This lawsuit arises in part from Apotex sending Plaintiffs, one of which is a Delaware corporate entity, a letter dated October 10, 2016 purporting to be a notification entitled, "ANDA No. 209434 (Mirabegron Extended-Release Tablets, 25 mg and 50 mg) Notification of Certification of Invalidity and/or Noninfringement of U.S. Patent Nos. 7,342,117; 7,982,049; RE44,872; and 8,835,474 Pursuant to § 505(j)(2)(B)(ii) of the U.S. Federal Food, Drug and Cosmetic Act" ("Notice Letter"). The Notice Letter is signed by an attorney for Apotex.

ANSWER: Without admitting that personal jurisdiction in this judicial district is proper, Apotex states that it does not contest personal jurisdiction for the purposes of this action only. Apotex denies all remaining allegations of Paragraph 16, except that the Notice Letter is signed by an attorney on behalf of Apotex.

17. When the Notice Letter was sent, Apotex knew or should have known that: (i) APGD is a Delaware corporation; and (ii) Plaintiffs would file suit against Apotex within 45 days of receiving the Notice Letter.

ANSWER: Denied.

18. Alternatively, assuming that the above facts do not establish personal jurisdiction over Apotex Inc., this Court may exercise jurisdiction over Apotex Inc. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Apotex Inc. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Apotex Inc. has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not admit that personal jurisdiction in this judicial district is proper, but does not contest personal jurisdiction for the purposes of this action only. Apotex denies all remaining allegations of Paragraph 18.

19. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not admit that venue is proper under 28 U.S.C. §§ 1391 and 1400(b), but does not contest venue for the purpose of this action only.

FACTUAL BACKGROUND

A. The '117 Patent

20. The PTO duly and legally issued the '117 patent, entitled "a-Form or ß-Form Crystal of Acetanilide Derivative," on March 11, 2008. A true and correct copy of the '117 patent is attached as Exhibit A.

ANSWER: Apotex admits that the '117 patent is titled "a-Form or ß-Form Crystal of Acetanilide Derivative," and that the face of the '117 patent indicates that it issued on March 11, 2008. Apotex respectfully refers the Court to the '117 patent for its true and complete contents and denies any allegation inconsistent therewith. Apotex denies any remaining allegations in Paragraph 20.

21. The '117 patent claims, *inter alia*, crystal forms of mirabegron.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 21, and on that basis denies these allegations. Apotex respectfully refers the Court to the '117 patent for its true and complete contents and denies any allegation inconsistent therewith.

22. The Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the expiration date of the '117 patent as November 4, 2023.

ANSWER: Admitted.

B. The '049 Patent

23. The PTO duly and legally issued the '049 patent, entitled "α-Form or ß-Form Crystal of Acetanilide Derivative," on July 19, 2011. A true and correct copy of the '049 patent is attached as Exhibit B.

ANSWER: Apotex admits that the '049 patent is titled "α-Form or ß-Form Crystal of Acetanilide Derivative," and that the face of the '049 patent indicates that it issued on July 19, 2011. Apotex respectfully refers the Court to the '049 patent for its true and complete contents and denies any allegation inconsistent therewith. Apotex denies any remaining allegations in Paragraph 23.

24. The '049 patent claims, *inter alia*, pharmaceutical compositions comprising crystal forms of mirabegron and a pharmaceutically acceptable carrier.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 24, and on that basis denies these allegations. Apotex respectfully refers the Court to the '049 patent for its true and complete contents and denies any allegation inconsistent therewith. Apotex denies any remaining allegations in Paragraph 24.

25. The Orange Book lists the expiration date of the '049 patent as November 4, 2023.

ANSWER: Admitted.

C. The ’474 Patent

26. The PTO duly and legally issued the ’474 patent, entitled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” on September 16, 2014. A true and correct copy of the ’474 patent is attached as Exhibit C.

ANSWER: Apotex admits that the ’474 patent is titled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” and that the face of the ’474 patent indicates that it issued on September 16, 2014. Apotex respectfully refers the Court to the ’474 patent for its true and complete contents and denies any allegation inconsistent therewith. Apotex denies any remaining allegations in Paragraph 26.

27. The ’474 patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 27, and on that basis denies these allegations. Apotex respectfully refers the Court to the ’474 patent for its true and complete contents and denies any allegation inconsistent therewith. Apotex denies any remaining allegations in Paragraph 27.

28. The Orange Book lists the expiration date of the ’474 patent as November 4, 2023.

ANSWER: Admitted.

D. The ’872 Patent

29. The PTO duly and legally re-issued the ’872 patent, entitled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” on April 29, 2014. A true and correct copy of the ’872 patent is attached as Exhibit D.

ANSWER: Apotex admits that the ’872 patent is titled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” and that the face of the ’872 patent indicates that it issued on April 29, 2014. Apotex respectfully refers the Court

to the ’872 patent for its true and complete contents and denies any allegation inconsistent therewith. Apotex denies any remaining allegations in Paragraph 29.

30. The ’872 patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron to adult subjects.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 30, and on that basis denies these allegations.

31. The ’872 patent also claims, *inter alia*, methods of treating overactive bladder by administering mirabegron, to non-adult subjects that are not suffering from diabetes.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 30, and on that basis denies these allegations. Apotex respectfully refers the Court to the ’872 patent for its true and complete contents and denies any allegation inconsistent therewith. Apotex denies any remaining allegations in Paragraph 31.

32. The Orange Book lists the expiration date of the ’872 patent as November 4, 2023.

ANSWER: Admitted.

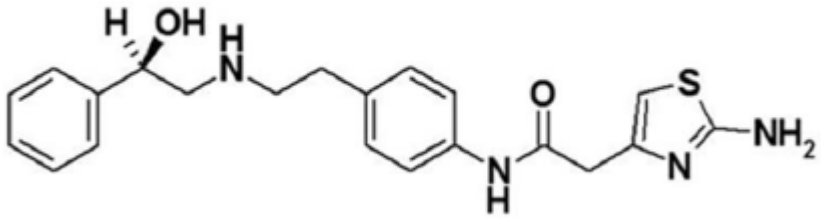
E. Myrbetriq®

33. APGD holds approved New Drug Application (“NDA”) No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient, mirabegron. The FDA approved NDA No. 202611 on June 28, 2012 for both the 25 mg and 50 mg extended-release Myrbetriq® tablets. In addition to the ’117, ’049, ’474 and ’872 patents, the Orange Book for NDA No. 202611 also lists, *inter alia*, U.S. Patent No. 6,346,532 (“the ’532 patent”) covering the mirabegron compound and pharmaceutical compositions containing mirabegron.

ANSWER: Apotex admits that the FDA’s electronic Orange Book lists APGD as the holder of NDA No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient, mirabegron. Apotex lacks knowledge or information sufficient to

form a belief as to the truth of all remaining allegations of Paragraph 33, and on that basis, denies all remaining allegations.

34. Mirabegron has been referred to chemically as, *inter alia*, (R)-2-(2 aminothiazol-4-yl)-4'-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, (R)-2-(2 aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, and 2-(2 aminothiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl]acetamide. Mirabegron can be depicted as, *inter alia*, the following formula:



ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 34, and on that basis denies these allegations.

35. Myrbetriq® extended-release tablets, 25 mg and 50 mg, are indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 35, and on that basis denies these allegations.

36. Astellas Pharma Inc. is the record owner and assignee of the '532, '117, '049, '474 and '872 patents.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 36, and on that basis denies these allegations.

37. AICL is the exclusive licensee of the '532, '117, '049, '474 and '872 patents with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 37, and on that basis denies these allegations.

38. APGD has contracted with Astellas Pharma US, Inc., a subsidiary of Astellas Pharma Inc., to market and sell Myrbetriq® extended-release tablets, 25 mg and 50 mg, in the United States on its behalf.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 38, and on that basis denies these allegations.

F. Infringement by Apotex

39. On information and belief, Apotex submitted to the FDA ANDA No. 209434 under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic mirabegron extended-release tablets in 25 mg and 50 mg strengths ("ANDA Product"), as a pharmaceutical composition in an oral dosage form for the treatment of overactive bladder prior to the expiration of the '117, '049, '474 and '872 patents.

ANSWER: Admitted.

40. On information and belief, Apotex intends to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the ANDA Product if and when it receives FDA approval to do so.

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent and answer is required, Apotex admits that it submitted to FDA ANDA No. 209434 seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic mirabegron extended-release tablets in 25 mg and 50 mg strengths. Apotex denies all remaining allegations of Paragraph 40.

41. The Notice Letter advised Plaintiffs that Apotex submitted ANDA No. 209434 to the FDA seeking approval to manufacture, use, offer to sell, sell, and/or import the ANDA Product prior to the expiration of the '117, '049, '474 and '872 patents. The Notice Letter advised Plaintiffs that Apotex's ANDA submission included a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Apotex's opinion, the claims of the '117, '049, '474 and '872 patents are invalid, unenforceable and/or not infringed.

ANSWER: Admitted.

42. The '532 patent is owned by Astellas Pharma Inc. and claims the compound mirabegron and compositions containing mirabegron, which is the active ingredient of Myrbetriq®. The ANDA Product is a composition that contains the compound mirabegron. On information and belief, Apotex made a "Paragraph III" certification with respect to the '532

patent, which includes certifying to the FDA that the '532 patent will expire on March 27, 2022, and that Apotex does not ask to have its ANDA approved before this date.

ANSWER: Apotex admits it made a Paragraph III certification with respect to the ’532 patent. Apotex lacks knowledge or information sufficient to form a belief as to the truth of all remaining allegations of Paragraph 42, and on that basis, denies all remaining allegations.

43. The submission of ANDA No. 209434 to the FDA constituted an act of infringement by Apotex of the ’117, ’049, ’474 and ’872 patents under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

44. Plaintiffs are commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER: Admitted.

CLAIMS FOR RELIEF

COUNT I: DIRECT INFRINGEMENT OF THE ’117 PATENT

45. Plaintiffs incorporate by reference and reallege paragraphs 1 through 44 above as though fully restated herein.

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. Apotex incorporates its answers to Paragraphs 1 to 44 as if fully set forth herein.

46. Pursuant to 35 U.S.C. § 271(e)(2), Apotex’s submission of ANDA No. 209434 to the FDA seeking approval of the ANDA Product was an act of infringement by Apotex of at least claim 1 of the '117 patent, which claims a crystal form of mirabegron that is contained in the ANDA Product.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 46.

47. The ANDA Product and the use thereof would infringe the '117 patent under 35 U.S.C. § 271(a), including at least claim 1, which covers, *inter alia*, a crystal form of mirabegron.

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 47.

48. Unless Apotex is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Apotex's infringement of the '117 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 48.

COUNT II: DIRECT INFRINGEMENT OF THE '049 PATENT

49. Plaintiffs incorporate by reference and reallege paragraphs 1 through 48 above as though fully restated herein.

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. Apotex incorporates its answers to Paragraphs 1 to 48 as if fully set forth herein.

50. Pursuant to 35 U.S.C. § 271(e)(2), Apotex's submission of ANDA No. 209434 to the FDA seeking approval of the ANDA Product was an act of infringement by Apotex of at least claims 1, 5, 9 and 13 of the '049 patent which claim pharmaceutical compositions comprising a crystal form of mirabegron and a pharmaceutically acceptable carrier contained in the ANDA Product.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 50.

51. The ANDA Product and the use thereof would infringe the '049 patent under 35 U.S.C. § 271(a), including at least claims 1, 5, 9 and 13, which cover, *inter alia*, pharmaceutical compositions comprising a crystal form of mirabegron and a pharmaceutically acceptable carrier.

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 51.

52. Unless Apotex is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Apotex's infringement of the '049 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 52.

COUNT III: DIRECT INFRINGEMENT OF THE '474 PATENT

53. Plaintiffs incorporate by reference and reallege paragraphs 1 through 52 above as though fully restated herein.

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. Apotex incorporates its answers to Paragraphs 1 to 52 as if fully set forth herein.

54. Pursuant to 35 U.S.C. § 271(e)(2), Apotex's submission of ANDA No. 209434 to the FDA seeking approval of the ANDA Product was an act of infringement by Apotex of at least claims 1, 3-4, 6-7, 9-10 and 12 of the '474 patent which cover the method of treating overactive bladder by administering mirabegron, the use for which Apotex seeks FDA approval in its ANDA.

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 54.

55. Unless Apotex is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Apotex's infringement of the '474 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 55.

COUNT IV: INDUCEMENT TO INFRINGE THE '474 PATENT

56. Plaintiffs incorporate by reference and reallege paragraphs 1 through 55 above as though fully restated herein.

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. Apotex incorporates its answers to Paragraphs 1 to 55 as if fully set forth herein.

57. Apotex has knowledge of the '474 patent.

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 57.

58. If the ANDA Product is approved by the FDA and is sold by Apotex, its use by healthcare providers and/or patients will directly infringe one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12.

ANSWER: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 58.

59. Apotex's proposed label for the ANDA Product explicitly instructs healthcare providers and/or patients to use the ANDA Product in a manner that will directly infringe one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12.

ANSWER: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 59.

60. Any use of the ANDA Product by patients will be performed at the direction and control of healthcare providers treating overactive bladder, who in turn are instructed by Apotex in its proposed label for the ANDA Product.

ANSWER: Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 60.

61. If the ANDA Product is approved by the FDA, Apotex will actively induce others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12. Apotex has acted with knowledge that the induced acts would constitute infringement of the '474 patent.

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 61.

62. Apotex specifically intends to cause direct infringement by others, e.g., healthcare providers and/or patients.

ANSWER: Paragraph 62 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 62.

63. If and when the FDA approves ANDA No. 209434, Apotex will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Apotex's proposed label, to use the ANDA Product in a manner that directly infringes one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9¬10 and 12. Thus, Apotex will aid, abet, urge, and/or encourage others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '474 patent, and Apotex will affirmatively and specifically intend to cause direct infringement.

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 63.

64. Apotex's actions will constitute inducement of infringement of the '474 patent pursuant to 35 U.S.C § 271(b).

ANSWER: Paragraph 64 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 64.

COUNT V: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT

65. Plaintiffs incorporate by reference and reallege paragraphs 1 through 64 above as though fully restated herein.

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. Apotex incorporates its answers to Paragraphs 1 to 64 as if fully set forth herein.

66. If ANDA No. 209434 is approved by the FDA, Apotex intends to and will offer to sell, sell, and/or import into the United States the ANDA Product.

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 66.

67. The ANDA Product constitutes a material part of the inventions covered by the claims of the '474 patent and has no substantial non-infringing uses.

ANSWER: Paragraph 67 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 67.

68. On information and belief, Apotex has had and continues to have knowledge that the ANDA Product is especially adapted for a use that infringes the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12.

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 68.

69. On information and belief, Apotex has had and continues to have knowledge that there is no substantial non-infringing use for the ANDA Product.

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 69.

70. Apotex's actions will constitute contributory infringement of the '474 patent pursuant to 35 U.S.C § 271(c).

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 70.

COUNT VI: DIRECT INFRINGEMENT OF THE '872 PATENT

71. Plaintiffs incorporate by reference and reallege paragraphs 1 through 70 above as though fully restated herein.

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. Apotex incorporates its answers to Paragraphs 1 to 70 as if fully set forth herein.

72. Pursuant to 35 U.S.C. § 271(e)(2), Apotex's submission of ANDA No. 209434 to the FDA seeking approval of the ANDA Product was an act of infringement by Apotex of at least claims 1, 3-4, 6, 8-9 and 11-14 of the '872 patent which cover the method of treating overactive bladder by administering mirabegron, the use for which Apotex seeks FDA approval in its ANDA.

ANSWER: Paragraph 72 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 72.

73. Unless Apotex is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Apotex's infringement of the '872 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 73.

COUNT VII: INDUCEMENT TO INFRINGE THE ’872 PATENT

74. Plaintiffs incorporate by reference and reallege paragraphs 1 through 73 above as though fully restated herein.

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. Apotex incorporates its answers to Paragraphs 1 to 73 as if fully set forth herein.

75. Apotex has knowledge of the '872 patent.

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 75.

76. If the ANDA Product is approved by the FDA and is sold by Apotex, its use by healthcare providers and/or patients will directly infringe one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14.

ANSWER: Paragraph 76 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 76.

77. Apotex’s proposed label for the ANDA Product explicitly instructs healthcare providers and/or patients to use the ANDA Product in a manner that will directly infringe one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14.

ANSWER: Paragraph 77 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 77.

78. Any use of the ANDA Product by patients will be performed at the direction and control of healthcare providers treating overactive bladder, who in turn are instructed by Apotex in its proposed label for the ANDA Product.

ANSWER: Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 78.

79. If the ANDA Product is approved by the FDA, Apotex will actively induce others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14. Apotex has acted with knowledge that the induced acts would constitute infringement of the '872 patent.

ANSWER: Paragraph 79 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 79.

80. Apotex specifically intends to cause direct infringement by others, e.g., healthcare providers and/or patients.

ANSWER: Paragraph 80 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 80.

81. If and when the FDA approves ANDA No. 209434, Apotex will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Apotex's proposed label, to use the ANDA Product in a manner that directly infringes one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14. Thus, Apotex will aid, abet, urge, and/or encourage others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '872 patent, and Apotex will affirmatively and specifically intend to cause direct infringement.

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 81.

82. Apotex's actions will constitute inducement of infringement of the '872 patent pursuant to 35 U.S.C § 271(b).

ANSWER: Paragraph 82 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 82.

COUNT VIII: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT

83. Plaintiffs incorporate by reference and reallege paragraphs 1 through 82 above as though fully restated herein.

ANSWER: Paragraph 83 contains legal conclusions and allegations to which no answer is required. Apotex incorporates its answers to Paragraphs 1 to 82 as if fully set forth herein.

84. If ANDA No. 209434 is approved by the FDA, Apotex intends to and will offer to sell, sell, and/or import into the United States the ANDA Product.

ANSWER: Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 84.

85. The ANDA Product constitutes a material part of the inventions covered by the claims of the '872 patent and has no substantial noninfringing uses.

ANSWER: Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 85.

86. On information and belief, Apotex has had and continues to have knowledge that the ANDA Product is especially adapted for a use that infringes the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14.

ANSWER: Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 86.

87. On information and belief, Apotex has had and continues to have knowledge that there is no substantial non-infringing use for the ANDA Product.

ANSWER: Paragraph 87 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 87.

88. Apotex's actions will constitute contributory infringement of the '872 patent pursuant to 35 U.S.C § 271(c).

ANSWER: Paragraph 88 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 88.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

Apotex denies that Plaintiffs are entitled to any of the relief requested in Paragraphs A–I of the Complaint's Prayer for Relief, or otherwise.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any averments of Plaintiffs' Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Apotex avers and asserts the following Affirmative Defenses to the Complaint:

FIRST DEFENSE

Apotex has not infringed and will not infringe any valid claim of the Asserted Patents directly, indirectly, contributorily, or by inducement, either literally or under the doctrine of equivalents.

SECOND DEFENSE

The claims of the Asserted Patents are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under other judicially-created bases for invalidation.

THIRD DEFENSE

Plaintiffs' Complaint, in whole or in part, fails to state a claim on which relief can be granted.

FOURTH DEFENSE

Any additional defenses that discovery may reveal.

Dated: January 17, 2017

Respectfully submitted,

/s/ John M. Seaman

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